DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19,2014

Noris Medical, Ltd.
Dr. Raanan Aloni
QA/RA Director
8 Hataasia Street
Nesher 3688808
ISRAEL

Re: K140440
Trade/Device Name: Noris Medical Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 19, 2014
Received: November 21, 2014

Dear Dr. Aloni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K140440__

Device Name: _Noris Medical Dental Implants System

Indications for Use:

Noris Medical Ltd Dental Implants System is intended to replace missing tooth/ teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Mono implants are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. They are used for immediate, non-occlusal provisionalization in single-tooth restorations. Multiple-unit restorations should be splinted together and may be used immediately when clinically appropriate.

Prescription Use __Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __No_____ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Noris Medical Dental Implants System

1. GENERAL INFORMATION

Date Prepared:	11th December 2014
	Noris Medical Dental Implants System
Common Name:	Endosseous Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Class:	II
Product Code:	DZE/NHA
CFR section:	21 CFR§872.3640
Device panel:	Dental
Legally Marketed Predicate Device:	K040807-MIS , K080162-MIS, K112440-A.B. dental, K132125-A.B.dental, K061477 Nobel Biocare
Submitter:	Noris Medical Ltd. 8 Hataasia street, Nesher 3688808, Israel
Contact:	Dr. Raanan Aloni, QA/RA Director E-mail: aloni@norismedical.com and Simha Sibony- Regulatory Affairs specialist E-mail: simha.qualitech@gmail.com Tel: +972-73-796-4477 Fax: +972-4-695-0991

2. DEVICE DESCRIPTION

The Noris Medical Dental Implants System consists of one or two stage endosseous form dental implants, internal hexagonal and one piece implants system

Abutments and Superstructures are used in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation.

The implantation procedure can be accomplished in a one-stage or two-stage surgical operation for all implants type beside the Mono which is for one stage only.

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2.A Implants sizes and dimensions:

Tuff Implants
With their three thread zones, Tuff implants have been uniquely designed according to the anatomy of the bone structure. The lower V-shape thread zone enables self-tapping. The middle zone square type thread is used for compressing cancellous bone. Micro threads are on the upper zone.

Diameter 3.3, 3.75, 4.2, 5mm Length 8, 10, 11.5,13,16 mm Diameter 6 mm Length 8, 10, 11.5,13 Made of titanium alloy Ti 6Al 4V ELI

Tuff TT Implants
Tuff TT Implants share the same three-thread zone concept as Tuff implants. The taper top converging coronal shape allows platform switch technology .

Diameter 4.2, 5 mm ; Length 8, 10, 11.5,13,16 mm Diameter 6 mm Length 8, 10, 11.5,13 Made of titanium alloy Ti 6Al 4V ELI

Onyx Implants
Onyx implants are specially designed for treatments involving placement in type I and type II bone.

Diameter 3.3, 3.75, 4.2, 5, mm Length 8, 10, 11.5,13, 16 mm Diameter 6 mm Length 8, 10, 11.5,13 Made of titanium alloy Ti 6Al 4V ELI

Mono Implants
Mono implants are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. The implants are cleared for immediate, non-occlusal provisionalization in single-tooth restorations. Multiple-unit restorations should be splinted together. In appropriate clinical conditions Mono Implants may be loaded immediately.

Diameter 3.0, 3.3, 3.75, 4.2 ; Length 10, 11.5, 13,16 mm Diameter 5 mm Length 10, 11.5, 13 mm Made of titanium alloy Ti 6Al 4V ELI

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The Noris Medical Dental Implants System includes prosthetics components that consist of healing caps, Cemented retained restorations: straight and angular abutments (narrow/narrow top/wide/shoulder/anatomic/esthetic abutment); Screw retained restorations: Multi unit, Esthetic screw abutments; Removable restorations : Vari connect abutments, Ball attachments, Flat attachments. Accessories: Cover screw, Angular Adaptor, Locator, transfer, Analog and others.

2.B Prosthetics size and dimensions

Healing Caps

Healing caps prepare the site for the superstructure insertion and "shapes" the soft tissue surrounding the implant.

Diameter 3.8, 4.6, 5.5, 6.3 mm; Length 2, 3, 4, 5, 6, 7 mm Made of titanium alloy Ti 6Al 4V ELI

Straight Abutments- cemented retained reconstruction

A wide variety of titanium straight abutments are available for use in different situations.

- Narrow abutments
- Wide abutments
- Anatomic abutments
- Narrow shoulder abutments

Diameter 5.2 mm; Length 9, 10, 11, 12 mm; shoulder 1, 2, 3, 4 mm Diameter 4.5 mm; Length 8.5, 9.5, 10.5, 11.5 mm; shoulder 1, 2, 3, 4 mm Diameter 4.5 mm; Length 8.5, 9.5, 10.5, 11.5, 12.5 mm Diameter 3.75 mm; Length 8.5 mm; shoulder 0.5, 1.5, 2.75 mm Diameter 3.8 mm; Length 6, 8 mm Diameter 5.5 mm; Length 9, 11 mm Made of titanium alloy Ti 6Al 4V ELI

*Implant – abutment connection i same 3.75mm platform for all abutments .

Angular Abutments - cemented retained reconstruction

The abutments are available with angles of 15° and 25° degrees.

- Angular, narrow abutments are used in minimal prosthetic space.
- Angular anatomic abutments have a shape that is contoured to the gingiva. This enables an individualization of the prosthetic unit. Variety of shoulder heights provides solutions for the alignment of the abutment with the soft tissue topography.
- Narrow top angular abutment allows minimal technical preparation.

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Anatomic - 15° and 25°:

Diameter 5.4 mm; Length 9.5, 10.5, 11.5, 12.5 mm; shoulder 1, 2, 3, 4 mm

Anatomic - 15°: Diameter 5.4 mm; Length 8.5 mm; shoulder 0.8 mm

Standard - 15° and 25°: Diameter 5.4 mm; Length 9, 11 mm

Narrow - 15°: Diameter 4 mm; Length 9 mm

Narrow Top - 15° and 25°: Length 9 mm

Made of titanium alloy Ti 6Al 4V ELI

Esthetic Abutments

The esthetic abutments are available in different shapes, sizes and angulations.

Straight - Diameter 5.4 mm; Length 8.5, 9.5, 10.5, 11.5 mm; shoulder 1, 2, 3 mm
Angulated - 15° and 25°: Diameter 4.5 mm; Length 9, 11 mm
Made of titanium alloy Ti 6Al 4V ELI

Color, using an anodizing technique, for categorical considerations only.

Esthetic Screw Abutments - screw retained restoration

Esthetic Screw Abutment is designed for the screw retained rehabilitation process on single or multiple units.

Base: Length 0.5, 1.5, 2.5 mm
Screw: Length 10.5, 11.5, 12.5 mm
Made of titanium alloy Ti 6Al 4V ELI

Plastic Castable Abutments on Titanium Bases enable the dental laboratory to cast on an accurate Titanium base. The machined Titanium base provides an accurate fit to the implant.

Hexed: Diameter 4.5 mm; Length 10.5 mm
Made of titanium alloy Ti 6Al 4V ELI + Delrin

No angular correction may be fabricated on Titanium base plastic castable abutments

Multi-Unit - screw retained reconstruction

The Multi-Unit system comprises a full range of sizes for both the upper and lower jaws. Straight, 17°, 30° adaptors, in a variety of heights, connects to a wide range of complementary products.

Straight – Length 1, 2, 3 mm Angulated 17° and 30° - Length 2, 3, 4 mm Made of titanium alloy Ti 6Al 4V ELI

Vari-Connect - screw retained or removable reconstruction

The Vari-Connect system presents a complete solution for removable prostheses on tilted implants. Straight, 17°, 30° adaptors are available. Complementary products are fixed to the adaptors by the adaptor thread.

Angulated 17° and 30° - Length 2, 3, 4 mm Made of titanium alloy Ti 6Al 4V ELI

Ball attachment - removable

The ball attachment superstructure is intended to secure a removable prosthesis.

Length; 0.5, 1, 2, 3, 4, 5, 6 mm Made of titanium alloy Ti 6Al 4V ELI

Flat attachment- removable

The Flat attachment superstructure is intended to secure a removable prosthesis.

Length; 0.5, 1, 2, 3, 4, 5 mm Made of titanium alloy Ti 6Al 4V ELI

Materials and Production:

The implants and prosthetic components are manufactured from Titanium alloy (Ti 6Al 4V ELI) complying with standard ASTM F 136 Standard *Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for surgical implant applications.* Noris Medical employs the SLA (Sandblasted, Large grit, Acid etched) surface treatment technology.
The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6} validated in compliance with ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices.*

3. INTENDED USE

Noris Medical Dental Implants System is intended to replace missing tooth/ teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical

operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Mono implants are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. They are used for immediate, non-occlusal provisionalization in single-tooth restorations. Multiple-unit restorations should be splinted together and may be used immediately when clinically appropriate.

4. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

Noris Medical Dental Implants System(Noris) is substantially equivalent to M.I.S K040807,and M.I.S. K080162 in terms of intended use, design, materials used, safety and performance testing.

Identification of the Legally Marketed Predicate Devices Used to Claim Substantial Equivalence:

Device Name	MIS Dental Implant System	Noris Medical Dental Implants System
510(k)Number	K040807 K080162(Uno)	K140440
Sponsor	M.I.S.	Noris Medical
Product Code	DZE/NHA	DZE/NHA
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals
Material	Titanium alloy	Titanium alloy
Diameter(mm)	**Biocom** 3.3, 3.75, 4.2, 5, 6. **Seven** 3.3, 3.75, 4.2, 5,6 **Uno** 3.0, 3.5	**Onyx** 3.3, 3.75, 4.2, 5, 6 **Tuff** 3.3, 3.75, 4.2, 5, 6 **Tuff TT** 4.2, 5, 6 **Mono** 3.0, 3.3,3.75,4.2,5
Length (mm)	**Biocom** 8, 10, 11.5, 13, 16 **Seven** 8, 10, 11.5, 13, 16 **Uno** 10,11.5, 13, 16	**Onyx** 8,10,11.5,13,16 Dia 6 –Length 8,10,11.5,13 **Tuff, Tuff TT** 8,10,11.5,13, 16 Dia 6 –Length 8,10,11.5,13

		Mono 10,11.5,13,16 Dia 5 –Length 10,11.5,13
Abutments°	0,15,25	0,15,17,25,30
Design	Root Form	Root Form
Prosthetic Connection	Internal Hex	Internal Hex
Sterility	Gamma irradiation	Gamma irradiation
Clinical procedure	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period

The prosthetics components of Noris Medical Dental Implants System are substantially equivalent to K112440-A.B. dental, K132125-A.B.dental, K061477 Nobel Biocare in terms of intended use, design, materials used, safety and performance testing.

Identification of the Legally Marketed Predicate Devices Used to Claim Substantial Equivalence:

Healing cap

	AB Dental	**Noris Medical**
Feature		
K510	K112440	Present submission
Product Name	P0-Healing Cap	Healing cap
Intended use	Used to allow the gingiva to heal around implants	Used to allow the gingiva to heal around implants.
Material	Titanium alloy	Titanium alloy
Diameter (mm)	3.75	3.8,4.6,5.5,6.3
Height (mm)	2,3,4,5,6,7	2,3,4,5,6,7
Angle	0	0
Sterility	Non sterile	Non sterile

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Straight abutment

	AB Dental	Noris Medical
Feature		
Product Name	P3 - abutment anti rotation	Straight abutment
K510	K112440	K140440
Intended use	The straight abutment is used in the fabrication of cement-retained restorations, single crowns or bridges.	The straight abutment is used in the fabrication of cement-retained restorations, single crowns or bridges.
Material	Titanium alloy	Titanium alloy
Diameter (mm)	3,3.75,5	3.75,3.8,4.5,5.2,5.5,9
Height (mm)	5,7,9,12,15	6,8,8.5,9,9.5,10,10.5,11,11.5,12,12.5,15
Angle	0	0
Sterility	Non sterile	Non sterile

Vari-connect

Feature	AB Dental	Noris Medical
K510	K132125	K140440
Product Name	P5-P14 Ball for Angular Adaptor	Vari-connect
Intended use	To connect a removable denture to an implant.	The Vari-Connect system is intended to connect a removable denture to an implant
Material	Titanium alloy	Titanium alloy
Diameter (mm)	3.5,3.9	4.8
Height (mm)	1,3	2,3,4
Angle (º)	17,30	0, 17, 30
Sterility	Non sterile	Non sterile

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Esthetic Screw Abutments

Feature	AB Dental	Noris Medical
K510	K132125	K140440
Product Name	P7 Anti-rotation Aesthetic Abutment,	Esthetic Screw Abutments
Intended use	Suitable for restorations of a single implant or screwed bridge on non-parallel implants	Esthetic Screw Abutment is intended for the screw retained rehabilitation process on single or multiple units.
Material	Titanium alloy	Titanium alloy
Diameter (mm)	3.75	4.7
Height (mm)	1,2,3	0.5,1.5,2.5
Angle (º)	0	0
Sterility	Non sterile	Non sterile

Ball attachment

Feature	AB Dental	Noris Medical
K510	K132125	K140440
Product Name	P5- Ball attachment abutment	Ball attachment
Intended use	To connect a removable denture to an implant	The ball attachment superstructure is intended to secure a removable prosthesis.
Material	Titanium alloy	Titanium alloy
Height (mm)	1,2,3,4,5,6	0.5,1,2,3,4,5,6,7
Angle (º)	0	0
Sterility	Non sterile	Non sterile

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Flat attachment

Feature	AB Dental	Noris Medical
Product Name	P55 low connector	Flat attachment
K510	K132125	K140440
Intended use	Over denture attachment system for easy connection between the denture and the implant	The Flat attachment superstructure is intended to secure an overdenture
Material	Titanium alloy	Titanium alloy
Diameter (mm)	3.75	3.75
Height (mm)	1,2,3,4,5,6,7,8	0.5,1,2,3,4,5
Angle (º)	0	0
Sterility	Non sterile	Non sterile

Multi-Unit

Feature	Nobel biocare	Noris Medical
K510	K061477	K140440
Product Name	Multi-unit	Multi-Unit
Intended use	Nobel Biocare's Multi-Unit Abutment is a premanufactured prosthetic component intended for use as an aid in prosthetic rehabilitation.	The Multi-Unit Abutment is a prosthetic device that fits only the 2.42 mm internal Hex implants. The device has been developed for long-term, permanent use. The Multi-Unit system provides a solution for screw-retained prosthetic rehabilitation
Material	Titanium alloy	Titanium alloy
Diameter (mm)	3.5,3.9	4.8
Height (mm)	2,2.5,3,3.5,4,4.5,5	1,2,3,4
Angle (º)	Up to 30	0, 17, 30
Sterility	Non sterile	Non sterile

Evidence of equivalence has been demonstrated through:

* The Noris Medical Dental Implants System intended use and indications for use were previously cleared by FDA for the predicate devices.
* The technical characteristics of the Noris Medical Dental implants System are similar to those of the predicate devices.
* Safety and performance testing of the Noris Medical Dental implants System are similar to those of the predicate devices.

Therefore, the Noris Medical Dental Implants System is substantially equivalent to the predicate devices in terms of intended use, materials used, and technological characteristics

4. NON-CLINICAL TEST

The components are manufactured from medical grade Titanium alloy (Ti 6Al 4V ELI) per ASTM F136.
SEM and Surface analysis (EDS) after SLA process demonstrated the morphology and cleanliness of the final product.

Sterilization validation tests were conducted in compliance with ANSI/AAMI/ISO 11137-1:06 and EN ISO 11137-2:12 in order to ensure safety and effectiveness related to Noris Medical Dental Implants System.
Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Accelerated aging per ASTM-F-1980:07 have been applied on the final packaging followed by validating durability to peel, dye and burst tests conditions in order to substantiate 5 years shelf life.

Static and dynamic compression performance test was conducted per ISO 14801: 07-Dentistry-Implants-Dynamic fatigue test for Endosseous Dental implants.
The worst case scenario was chosen based on the FDA guideline "Class II Special Controls Guidance Document: Root form for Endosseous dental implants and Endosseous dental Implant Abutments".

The results of the testing indicate that the Noris Medical Dental Implants System is substantial equivalent to the predicate devices sighted in this submission.

5. CLINICAL TEST

No clinical studies were performed.

6. CONCLUSION

The results of the testing conducted on the Noris Medical Dental Implants System demonstrated that the system is substantially equivalent to the named predicated devices in terms of functional, mechanical properties, indications for use and material.